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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,574	06/11/2001	Francis Sullivan	GFN-5285D3CPACN	4282

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EXAMINER	
PAK, YONG D	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	09/878,574	SULLIVAN ET AL.	
	Examiner	Art Unit	
	Yong D Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 21-42* is/are pending in the application.

4a) Of the above claim(s) *9,22,24,25 and 30-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21, 23, 26-29 and 38-39* is/are rejected.

7)☒ Claim(s) *40-42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This application is a continuation of 09/333,177, which is a divisional of 09/149,674, which is a divisional of 08/984,246, which is a divisional of 08/753,233.

The amendment filed on August 22, 2003, amending claim 26 and 27 and adding claims 38-42, has been entered.

Claims 9 and 21-42 are pending.

Election/Restrictions

Claims 9, 22, 24-25 and 30-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Response to Arguments

Applicant's arguments with respect to claims 21, 23 and 26-29 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 23, 26-29 and 38-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 21, 23 and 26-28 are drawn to a process of treating inflammatory disorder or modulating an inflammatory response using a genus of modulators/inhibitors of any GDP-mannose-4,6-dehydratase (GM4,6D). The claimed invention is drawn to a method of treatment that requires the use of undisclosed modulators/inhibitors. There is insufficient descriptive support for the genus of modulators/inhibitors. The specification does not disclose structural identifying characteristics of the genus of modulators/inhibitors. The specification only describes a method of treatment using antibodies of the GM4,6D of SEQ ID NO:2 or 3. There is no evidence that there is any per se structure/function relationship between the disclosed modulator/inhibitor compounds in the genus. In order to evidence possession of the claimed method, one would need to demonstrate possession of its process steps which requires the use of undisclosed compounds. Also, there is no evidence on the record of the relationship between the structure of a modulator/inhibitor of one species of GM4,6D and a modulator/inhibitor of SEQ ID NO:2 and 3. The rejection might be overcome by showing of objective evidence that supports the proposition that the particularly disclosed modulators were representative of the structure of the group of molecules.

Claim 38-39 are drawn to a process of treating inflammatory disorder or modulating an inflammatory response using a genus of inhibitors of the GDP-mannose-4,6-dehydratase (GM4,6D) of SEQ ID NO:2 or 3. The claimed invention is drawn to a method of treatment that requires the use of undisclosed modulators/inhibitors. There is insufficient descriptive support for the genus of modulators/inhibitors. The specification does not disclose structural identifying characteristics of the genus of modulators. There is no evidence that there is any per se structure/function relationship between the disclosed modulator/inhibitor compounds in the genus. In order to evidence possession of the claimed method, one would need to demonstrate possession of its process steps which requires the use of undisclosed compounds. The rejection might be overcome by showing of objective evidence that supports the proposition that the particularly disclosed modulators were representative of the structure of the group of molecules.

Claim 29 is drawn to a process of treating inflammatory disorder or modulating an inflammatory response using a genus of antibody against any GDP-mannose-4,6-dehydratase (GM4,6D). The claimed invention is drawn to a method of treatment that requires the use of undisclosed antibodies. There is insufficient descriptive support for the genus of antibodies. The specification does not disclose structural identifying characteristics of the genus of antibodies. There is no evidence that there is any per se structure/function relationship between the disclosed antibody compounds in the genus. The specification only describes a method of treatment using antibodies of the GM4,6D of SEQ ID NO:2 or 3. In order to evidence possession of the claimed method, one

would need to demonstrate possession of its process steps which requires the use of undisclosed compounds. There is no evidence on the record of the relationship between the structure of an antibody of one species of GM4,6D and an antibody of SEQ ID NO:2 and 3. The rejection might be overcome by showing of objective evidence that supports the proposition that the particularly disclosed antibodies were representative of the structure of the group of molecules.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 21, 23, 26-29 and 38-39.

Claims 21, 23, 26-29 and 38-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a subject with antibodies against the GM4,6D of SEQ ID NO:2 and 3, does not reasonably provide enablement for treating a subject with any modulators/inhibitors against GM4,6D or antibodies against GM4,6D different from SEQ ID NO:2 and 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of

direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claimed invention is drawn to a method of treatment that requires the use of undisclosed modulators/inhibitors/antibodies. There is insufficient descriptive support for the genus of modulators/inhibitors/antibodies. The specification does not disclose structural identifying characteristics of the genus of modulators/inhibitors/antibodies. The specification only teaches a method of treatment using antibodies of the GM4,6D of SEQ ID NO:2 or 3. One of ordinary skill in the art would not know the identify of a reasonable number of representative compounds falling within the scope of the instant claims and consequently would not have know how to make them. An assay for finding a product is not equivalent to a positive recitation of how to make a product.

Therefore, one of ordinary skill would require guidance in order to treat a subject with modulators against GM4,6D of SEQ ID NO:2 and 3 and antibodies against GM4,6D different from SEQ ID NO:2 and 3 in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 23 and 26-29 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the therapeutically effective amount of the antibodies/inhibitors/modulators needed to treat a subject having inflammatory disorder.

Allowable Subject Matter

Claims 40-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

November 17, 2003